IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.: 10/679,006	TC/A.U.: 1655
Applicant: Bobrowski, Paul J.	Examiner: Meller, Michael V.
Filed: October 04, 2003	Docket No.: PHMC0745-025
Cust. No.: 26948	Confirmation No. 8907

Appl. Title: PHARMACEUTICAL PREPARATIONS FOR THE TREATMENT OF ITCH, NAUSEA, HYPERALGESIA AND THE COMPLICATIONS OF OPIOID AGONISTS

APPELLANT'S BRIEF

This is an appeal from the Office Action dated July 1, 2008, which included the final rejection of Claims 10, 12-14 and 19-27. This is the second appeal in this application. The first appeal resulted in a reversal of the Examiner's reasons for rejection of the claims and the issuance of a new rejection of the claims. (Appeal 2008-0508, p. 11-12) Prosecution was reopened under 37 CFR § 41.50(b) to address the new rejection. (Response dated 2008-05-29, p. 5) The requisite fee for the Notice of Appeal was filed on October 2, 2008; and the requisite fee for this Brief is submitted herewith.

REAL PARTY IN INTEREST (37 C.F.R. 41.37(C)(1)(I))

Rainforest Nutritionals, Inc., an Arizona Corporation residing in the state of North Carolina, is the real party in interest.

RELATED APPEALS AND INTERFERENCES (37 C.F.R. 41.37(C)(1)(II))

This is the second appeal in this application. The first appeal resulted in a reversal of the Examiner's rejection and a new rejection of the claims. (Appeal 2008-0508, p. 11) Prosecution was reopened under 37 CFR § 41.50(b). (Response dated 2008-05-29, p. 5)

STATUS OF CLAIMS (37 C.F.R. 41.37(C)(1)(III))

The current status of the claims is as follows:

No claims are allowed.

No claims have been objected to.

Claims 1-9, 11, and 15-18 have been cancelled.

Claims 10, 12-14 and 19-27 are subject to rejection.

Claims 10, 12-14 and 19-27 are subject to appeal.

STATUS OF AMENDMENTS (37 C.F.R. 41.37(C)(1)(IV))

After the Final Office Action of July 1, 2008, the Applicant has not amended any pending claims. The Applicant's last amendment was filed on May 29, 2008; claims 10, 12, 13, 14, 19, 20 - 24 were amended; claims 25-27 were added. Claims 1-9, 11, and 15-18, are cancelled.

SUMMARY OF CLAIMED SUBJECT MATTER (37 C.F.R. 41.37(C)(1)(V))

Claims 10 & 12

Claim 10 is an independent claim and comprises a lipophilic extract of latex from family Euphorbaciae, species Croton (Spec., ¶ 10) that, at a concentration of 1 mg of the extract in 1mL of water, has light absorbency reduced by a factor of about at least 4.3 between the range of 390 nm and 430nm relative to the light absorbency within the same range for 1mg of latex from family Euphorbaciae, species Croton (Id., ¶s 24-28). The extract reduces at least one symptom (e.g. nausea, emesis, retching, and itch) associated with opiods. (Id., ¶s 11-12)

Claim 12 depends from claim 10. The invention of claim 12 specifies that the absorbency between the range of 390 nm and 430 nm is less than 21% of the light absorbency of latex from family Euphorbaciae, species Croton. (Id., ¶s 18, 53, 54, Figure 6.)

Claims 13, 14, 19-24

Claim 13 is an independent claim and comprises a lipophilic extract of the latex from Croton species of the family Euphorbaciae that reduces the effect of hyperalgesia (Id., ¶s 12, 16, 35, 44 - 47, and Figure 6), and which, at a concentration of about 1mg of the lipophilic extract to 1 mL of water has reduced light absorbency in the range of 390nm to 430nm of at least 4.3 relative to the same concentration of 1mg of latex from Croton species of the family Euphorbaciae in 1 mL of water (Id., ¶s 53-54).

Claim 14 depends from claim 13 and specifies that the carrier is aloe barbadensis. (Id., ¶s 54-55)

Claim 19 depends from claim 13 and specifies the lipophilic extract in claim 13 and specifies the lipophilic extract in claim 13 in a pharmaceutical dosage that reduces opioid-induced nausea, emesis, retching and itch. (Id., ¶s 11-12)

Claim 20 depends from claim 13 and specifies the lipophilic extract in claim 13 in a pharmaceutical dosage that reduces motion sickness. (Id., ¶ 35)

Claim 21 depends from claim 14 and specifies that the lipophilic extract is no more than 10 % by volume relative to the quantity of aloe barbadensis.

Claim 22 depends from claim 13 and specifies that the lipophilic extract has proanthocyanidin content is reduced at least 50% relative to the proanthocyanidin content of the latex from Croton species from family Euphorbaciae. (Id., ¶s 18-22, 25-33, 43)

Claim 23 depends from claim 10 and specifies that the lipophilic extract is administered orally at a concentration of at least 2 mg/kg of bodyweight. (Id., ¶s 14, 19, 37-40, 57)

Claim 24 depends from claim 10 and specifies that the proanthocyanidin content of the lipophilic extract is reduced at least 50% relative to the proanthocyanidin content of the latex from family Euphorbacie species Croton. (Id., ¶s 18-22, 25-33, 43)

Claims 25-27

Claim 25 is an independent claim for a composition comprising the lipophilic components from Croton species latex made by mixing Croton latex and organic solvent to resolve aqueous and organic fractions, filtering the aqueous and and organic fractions to remove the aqueous fraction reserve the organic fraction, and drying the organic fraction comprising the lipophilic components. (Id., ¶s 22-34) At a concentration of 1 mg of the composition in 1 mL of water, the lipophilic extract has 33% of light absorbency at 414 nm relative to 1 mg of Croton latex in 1 mL of water. (Id., ¶s 53-54)

Claim 26 depends from claim 25 and specifies that the Croton latex and organic solvent are mixed in equal parts. (Id., ¶ 24)

Claim 27 depends from claim 26 and specifies that the light absorbency of 1 mg of the composition in 1 mL of water is less than 25% of the light absorbency of 1 mg of Croton latex in 1 mL of water. (Id., ¶ 30, 53-54, Fig. 6)

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
(37 C.F.R. 41.37(C)(1)(VI))

Whether claims 10, 12 - 15, and 19-27 are unpatentable under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter the applicant regards as the invention.

ARGUMENT (37 C.F.R. 41.37(C)(1)(VII))

I. THE CLAIMS PRECISELY DESCRIBE THE SUBJECT MATTER OF THE CLAIMS

The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). The Federal Circuit emphasized that the measure of definiteness is whether the claim delineates the bounds of the invention to a person of ordinary skill. *See, Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464 (Fed. Cir. 1993).

The invention pertains to a lipophilic extract of latex from the species Croton, family Euphorbaciae. (Spec., claim 10) The lipophilic extract is defined by the measure of reduced proanthocyanidin content resulting after the extraction process. (Id.) The reduced proanthocyanidin content is quantifiable spectrophotometrically. (Spec., ¶¶ 29-30) Particularly, 1 mg of the lipophilic extract in 1 mL of water absorbs about at least 4.3 times less light between the range of 390 nm and 430 nm wavelength than 1 mg of latex in 1 mL of water. (Id., claims 10, 13) Alternatively described, the extract has less than 21 % of the light absorbency than the unprocessed latex. (Id., claim 12) Or, the extract has proanthocyanidin content reduced at least 50% relative to the proanthocyanidin content of unprocessed latex from the species Croton, family Euphorbaciae. (Id., claims 22, 24) The extract is combinable with a carrier such as aloe barbadensis to tread itch (id., claims 14, 19, 21), or ingestible (i.e. at a concentration of at least 2 mg/kg bodyweight (id., claim 23)) to treat other illness. (Id., claims 19, 20) The lipophilic extract having reduced color content is also alternately specified by the solvents and process by which it is made. (Id., claims 25-27) In particular, an organic solvent and filtering are used to separate and reserve the organic fraction from the aqueous fraction. (Id., claim 25) Equal parts of Croton latex and organic solvent can be used in the process to make the extract. (Id., claim 26)

In the first appeal, the Board determined that the claim language was indefinite because it did not specify the baseline measurement or the plant material used to make the extract. (Appeal, 2008-0580, p. 7) For the purposes of this application, the Applicant has amended the claim to specify the plant material is latex. (Response dated 5-29-2008). [1] But, Applicant disputes that the lack of specifying the baseline absorbency measurement renders the claims indefinite. Patents are written for persons experienced in the field of the invention. *See Vivid Technologies, Inc. v. American Science and Engineering, Inc.*, 200 F.3d 795, 804 (Fed. Cir. 1999). The baseline measurement of the light absorbency of unprocessed latex from species Croton, family Euphorbaciae is measurable and within the knowledge of one of ordinary skill in the art. It follows that the scope of the claims is readily determinable.

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[1] Applicant disputes that the term "plant material" is indefinite. "Plant material" is a broader term that includes "latex", but breadth is not indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971); MPEP 2173.04. The Applicant may pursue the broader claim scope in a subsequent application.

Here, the specification teaches a person of ordinary skill in the art that latex of species Croton, family Euphorbiaccae, is derived from the Croton species of the Amazon River basin. (Spec., ¶ 6) The applicant's disclosure is consistent with prior art disclosures. (See, U.S. Pat. No. 3694557 issued to Persinos, Col. 3, lines 45-52) ("material of the invention is obtained [from] *Croton lechleri*, M. Arg. Family Euphorbiacae, to produce a sap which is in the form of a red, viscous exudates") Thus, a person of ordinary skill could identify latex of species Croton, family Euphorbiaccae and have basic knowledge of its color characteristics or the ability to measure the same. *See*, *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1382 (Fed. Cir. 1999) (a person of ordinary skill in the art is presumed to have knowledge of that which is known in the art). The specification and certain claims (i.e. claims 25-27) also describe how to alter the Croton latex to make the lipophilic extract of the invention. Specifically, latex, or sap from Croton species is mixed with an organic solvent. (Spec., ¶ 24; claims 25-27) For example, the organic solvent is added to the latex in a 1:1 proportion. (Id.) The lipophilic materials are solutes contained within the organic solvent which are concentrated by evaporation of the organic solvent. (Id., ¶ 28) The resulting lipophilic extract is defined by the change in the color characteristics, as defined by reduced absorbency or reduced proanthocyanidin content of the extract relative to the non extracted plant material, and the retained ability to treat opiod-induced symptoms.

The measure of reduced color pigmentation or proanthocyanidin content is confirmed by the reduced absorbency of the processed extract by introducing the 1mg of extract into 1 mL of water and comparing it to the absorbency of the unprocessed Croton latex. Or as explained in the specification: [a]t a concentration of 1 mg of extracted latex to 1 mL of water the disclosed process yielding the extraction (CGO 110) results in a 4.3 fold reduction in absorbance at 414 nm, as indicated in Figure 1. (¶ 30) In mathematical form:

$$\frac{\text{Absorbency of unprocessed Croton latex}}{4.3} \geq \text{Absorbency of extract}$$

Alleged Ambiguity - Relative measurements

The Board alleged that claim 10 is indefinite because "one of ordinary skill in the art could not determine the baseline measurement." (Appeal 2008-0508, p. 8) The Assignee disagrees with the Board's conclusion. "Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehar*t, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought." See, MPEP 2173.01

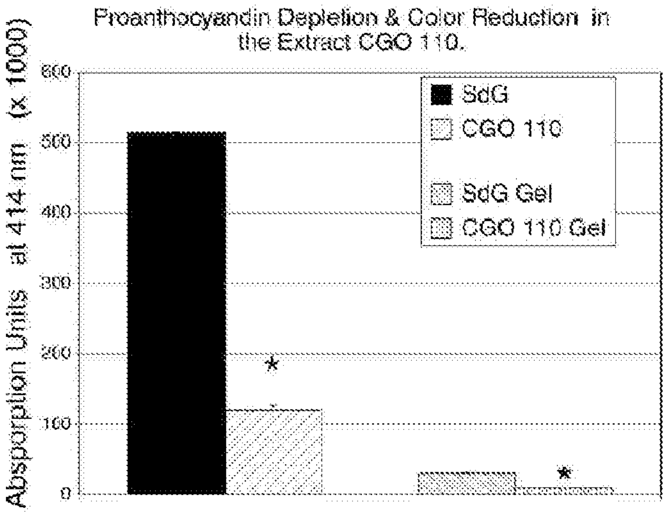
Here, a person of ordinary skill would recognize that the claimed subject matter is defined by the difference in light absorbency, or the difference in the proanthocyanidin content, between the lipophilic extract and the unprocessed Croton latex. Particularly, the claimed subject matter is an extract of Croton plant material having reduced color pigment components that absorb light within the range 390 nm and 430 but which retains beneficial medicinal properties. The extract is useful for topical applications and ingestion and avoids staining clothing or the mouth by the color pigment components that absorb light within the range 390 nm and 430. (Spec., ¶ 11)The reduction of color pigments is measurable by the comparison of the extract against the light absorbency of the same quantity of unprocessed Croton plant latex with color pigment that absorbs light within the range 390 nm and 430 intact or not reduced. The claim reflects the specification description of the reduced light absorbency of the extract.

That the PTO or Board considers the claim practically difficult to apply to the prior art does not render the claims indefinite if there are practicable means of detecting infringement. *See Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5.F3d 1464 (Fed. Cir. 1993); *also, See Gould Inc. v. Graphic Controls, Corp.*, 196 USPQ 13 (N.D. Ill. 1977) For the purposes of determining the scope of the claims and the light absorbency of the lipophilic Croton species extract is quantified by combining 1 mg of extract to 1 mL of water, and measuring the light absorbency using a spectrophotometer. The light absorbency of the unprocessed Croton latex is quantified by combining 1mg of Croton species latex to 1 mL of water and measuring the light absorbency. The quantified light absorbencies of the extract and Croton plant latex are then compared and expressed in terms of a ratio (see below) or a relative or reduced absorbency. Contrary to the Board's determination, the baseline measurement *is* present because the absorbency is expressed as a *relative* reduction. But, it should not matter whether the baseline is present provided that the claim describes to a person of ordinary skill in the art the scope of the claims: would a claim for a technology that "doubled the efficiency" of an engine be indefinite because the claim did not specify the *baseline* efficiency for an engine? Much like the baseline absorbency of the unprocessed Croton latex, the baseline efficiency of an engine is a measurable characteristic.

Alleged Ambiguity - "the claim does not define 4.3"

The Board also alleges that claim 10 is indefinite because "the claim does not define 4.3." (Appeal 2008-0580, p. 8-9) The Assignee disagrees that the term "4.3" or "4.3 fold reduction" needs definition in the claim or renders the claim indefinite. A person of ordinary skill would understand that a "4.3 reduction in absorbency" describes a composition having about 23% (i.e. 1/4.3) of the pre-reduced (baseline) absorbency. The term "4.3" as used in the claim to define the reduced absorbency is not "insolubly ambiguous". *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("[t]he requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles...[o]nly when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite"). The specification provides sufficient teaching to permit a person of ordinary skill to understand the claimed relative reduction.

Figure 6 describes the measured absorbencies of samples of extracted and unprocessed Croton plant latex. (Specification, Figure 6, (reproduced below))



The bar labeled "SdG" is the measured baseline or reference absorbency for a sample of unprocessed Croton plant latex. The SdG absorbency measurement at 414 nm is about 515 AU. The bar labeled "CGO 110" is the measured absorbency of the extracted Croton plant latex. The CGO 110 absorbency measurement at 414 nm is about 110 AU. The reduced absorbency of the Croton plant latex (CGO 110) expressed as a ratio to the unprocessed Croton plant latex is:

$$\frac{110\text{ AU}}{515\text{ AU}} \approx \frac{1}{4.7} \approx 0.21 \text{ or } 21\%$$

Alternatively, as claimed, the absorbency of the Croton plant material extract is reduced by a factor of at least 4.3 relative to the unprocessed Croton plant latex. The claims dependent from claim 10 are not indefinite for the same reason.

Claims 13, 14, 19, and 20-22

The Board also rejected claims 13, 14, 19, and 20-22 on the basis that the claims suffered the same alleged deficiencies as claims 10, 12, 23 and 24. (Appeal 2008-0580, p. 10) Assignee reiterates the arguments of the previous section herein. The claims are amended to more particularly define that the unprocessed baseline comparison plant material and extract are from Croton plant material latex. Further, the baseline or reference for the extract is incorporated in the claim since the reduced absorbency is defined in relative terms to the unprocessed Croton latex. Particularly, the claims specify that the relative reduction of the color pigment is quantified by comparison to the absorbency of 1 mg of latex extract and unprocessed Croton plant latex in 1 mL of water.

Claims 25-27

Claims 25-27 are new and require that the extract be made by a process consistent with the teachings of the specification and have less than 33% of the light absorbency of the unprocessed parent latex at 414 nm. Claim 26 further requires that the process use using equal parts of latex and organic solvent. Claim 27 further requires that the light absorbency of the extract in claim 26 is less than 25% of the unprocessed Croton plant latex.

The Examiner alleges that there is insufficient support for the percentages expressed in the claims. As disclosed by Figure 6 (included above) however, the specification supports light absorbency reductions at 414nm by as much as about 21%. The rejection is improper.

Respectfully submitted,

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CLAIMS APPENDIX (37 C.F.R. 41.37(C)(1)(VIII))

Claim 1 (withdrawn): A method of suppressing sensory afferent nerve mediated events in mammals comprising the application of a preparation including an extract from family Euphorbaciae having reduced proanthocyanidin content and concentrated lipophilic constituents.

Claim 2 (withdrawn): The method in claim 1 wherein the extract is created by:

combining plant material from the family Euphorbaciae with an organic solvent;

agitating the combination;

settling the combination into distinct phases to resolve a layer substantially comprised of hydrophilic constituents and an organic layer substantially comprised of lipophilic constituents; and,

evaporating the organic layer to resolve the lipophilic constituents.

Claim 3 (withdrawn): The method of claim **2** wherein the plant material is either the viscous latex or at least partially dried latex from the family Euphorbaciae.

Claim 4 (withdrawn): The method of claim **2** wherein the organic solvent is selected from the group consisting of ethyl acetate, isopropanol and chloroform/Methanol mixture.

Claim 5 (withdrawn): The method of claim **2** further comprising,

adding a drying agent to the settled organic layer, prior to the step of evaporating the organic layer, to further precipitate any remaining hydrophilic constituents, and filtering the organic layer to resolve the lipophilic constituents.

Claim 6 (withdrawn): The method in claim **6** wherein the drying agent is selected from the group consisting of magnesium sulfate and sodium sulfate.

Claim 7 (withdrawn): The method in claim **7** wherein the drying agent is magnesium sulfate and the amount added is between about five hundred milligrams (500 mg) to five grams (5 g) per liter of organic layer.

Claim 8 (withdrawn): The method in claim **6** wherein, after the step of filtering the organic layer, the organic layer at a concentration of one milligram per milliliter (1mg/mL) of 50% (v/v) ethanol/water has an absorbance of about 0.120 Abs Units in the wavelength range between about 390 nm and about 430 nm, relative to an absorbency of about 515 Abs Units within the same wavelength range.

Claim 9 (withdrawn): The method of claim **2** wherein the proanthocyanidin components are reduced by at least about 100 milligrams per gram relative to the parent latex.

Claim 10 (previously amended): A lipophilic extract of latex from family Euphorbaciae and species Croton that reduces at least one opioid-induced complication selected from the group consisting of; nausea, emesis, retching and itch, the lipophilic extract at a concentration of 1 mg of the lipophilic extract in 1 mL of water having light absorbency reduced by a factor of_about at least 4.3 between the range of 390 nm and 430 nm relative to the light_absorbency within the range of 390 nm and 430 nm for 1mg of latex from family Euphorbaciae and species Croton in 1 mL of water.

Claim 11 (canceled).

Claim 12 (previously amended): The extract in claim **10** wherein the absorbency between the range of 390 nm and 430 nm is about less than 21 % of the light absorbency of latex from family Euphorbaciae and species Croton.

Claim 13 (previously amended): A lipophilic extract of latex from species Croton family Euphorbaciae that reduces the effect of hyperalgesia, which at a concentration of about 1mg of the lipophilic extract to 1mL of water has reduced light_absorbency in the range of 390nm to 430nm of at least 4.3 relative to 1mg of latex from species Croton family Euphorbaciae in 1 mL of water.

Claim 14 (previously amended): The lipophilic extract in claim **13** wherein the lipophilic extract is combined with aloe barbadensis.

Claims 15 - 18 (canceled).

Claim 19 (previously amended): The lipophilic extract in claim **13** comprising a pharmaceutical dosage that reduces opioid-induced nausea, emesis, retching and itch.

Claim 20 (previously amended): The lipophilic extract in claim **13** comprising a pharmaceutical dosage that reduces motion sickness.

Claim 21 (previously amended): The lipophilic extract in claim **14** wherein,

the lipophilic extract comprises no more than 10% by volume relative to quantity of aloe barbadensis.

Claim 22 (previously amended): The lipophilic extract in claim **13** wherein,

the lipophilic extract has proanthocyanidin content reduced at least 50% relative to the proanthocyanidin content of latex from species Croton family Euphorbaciae.

Claim 23 (previously amended): The lipophilic extract in claim **10** wherein,

the lipophilic extract is administered orally at a concentration of at least 2 mg/kg of bodyweight.

Claim 24 (previously amended): The lipophilic extract in claim **10** wherein,

the lipophilic extract has proanthocyanidin content reduced at least 50% relative to the proanthocyanidin content of latex from family Euphorbaciae and species Croton.

Claim 25 (new): A composition that reduces the symptoms of nausea, emesis, retching, and itch, comprising lipophilic components from Croton latex made by mixing Croton latex and organic solvent to resolve aqueous and organic fractions, filtering the aqueous and organic fractions to remove the aqueous fraction and reserve the organic fraction, and drying the organic fraction comprising the lipophilic components, and wherein the light absorbency at 414 nm of 1 mg of the composition in 1 mL of water is less than 33% of the absorbency of 1 mg of Croton latex in 1 mL of water.

Claim 26 (new): The composition in claim **25** wherein,

the Croton latex and organic solvent are mixed in equal parts.

Claim 27 (new): The composition in claim **26** wherein,

the light absorbency of 1 mg of the composition in 1 mL of water is less than 25% of the light absorbency of 1 mg of Croton latex in 1 mL of water.

EVIDENCE APPENDIX (37 C.F.R. 41.37(C)(1)(IV))

RELATED PROCEEDINGS APPENDIX (37 C.F.R. 41.37(C)(1)(IV))

This is an appeal from the Office Action dated July 1, 2008, which included the final rejection of Claims 10, 12-14 and 19-27. There are no related pending appeals; however this is the second appeal in this application. The first appeal resulted in a reversal of the Examiner's reasons for rejection of the claims and the issuance of a new rejection of the claims. (Appeal 2008-0508, p. 12) Prosecution was reopened under 37 CFR § 41.50(b) to address the new rejection. (Response dated 2008-05-29, p. 5)